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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/575,699	01/03/2007	Lutz Biedermann	57540/B885	5534

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EXAMINER	
FISHER, ELANA BETH	

ART UNIT	PAPER NUMBER
3733	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/575,699	BIEDERMANN ET AL.	
	Examiner	Art Unit	
	ELANA B. FISHER	3733	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 April 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *4-9,12-18 and 23-34* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *4-9,12-18 and 23-34* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Transitional After Final Practice

1. Since this application is eligible for the transitional procedure of 37 CFR 1.129(a), and the fee set forth in 37 CFR 1.17(r) has been timely paid, the finality of the previous Office action is hereby withdrawn pursuant to 37 CFR 1.129(a). Applicant's first submission after final filed on April 19, 2010 has been entered.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claim 8 recites the limitation "the wall" in the third line of the claim. There is insufficient antecedent basis for this limitation in the claim.

4. Claims 4-5, 16-18, and 26 recite the limitation "the tubular body" in the second lines of the claims. There is insufficient antecedent basis for this limitation in the claims, since it is unclear as to which previously claimed tubular body the claims are referring to.

**Examiner notes that independent claims 23 and 24 each refer to a flexible tubular body with a helical recess as part of the connection element and as part of the space holder. Many of the dependent claims refer to the flexible tubular body and the helical recess. However, it is unclear as to which flexible tubular body and which helical recess the claims are referring to. Please clarify accordingly.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 4-9, 12-18, and 23-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Struder (PCT Publication PCT/CH02/00180) in view of Ferree (U.S. Publication 2003/0220643) and Gordon (U.S. Patent 6,949,686).

Struder discloses a spiral implant system bone anchoring device for spinal stabilization comprising: a bone anchoring device comprising a first bone anchoring element (12) for anchoring to a bone or vertebrae, the first bone anchoring element having a first receptacle (13); a second bone anchoring element (12) for anchoring to a bone or vertebrae, the second bone anchoring element having a second receptacle (13); a connection element (FIG 1) configured to connect the first bone anchoring element to the second bone anchoring element (FIG 2).

The connection element comprises a first rigid part (5) having a first rigid tubular body (16) configured to connect to the first bone anchoring element, the first rigid tubular body (16) having a first connection end (20) configured to be received in the first receptacle and at least one opposing threaded end (18). Additionally, there is a second rigid part (6) having a second rigid tubular body (17) configured to connect to the second bone anchoring element, the second rigid tubular body having a second connection end (20) configured to be received in the second receptacle and at least one opposing threaded end (18). The connecting element (FIG 1) further comprises a flexible part (2) having a first threaded end (24) and a second threaded end (24) defining a length of the flexible part and comprising a tubular body having a helical recess (FIG 5); and wherein the first

threaded end of the flexible tubular body is configured to connect to the at least one threaded end of the first rigid tubular body, and wherein the second threaded end of the flexible tubular body is configured to connect to the at least one threaded end of the second rigid tubular body (FIG 3).

The helical recess in the tubular body (FIG 3) is configured to provide an elasticity or a movement function, and the tubular body is configured as at least one of compression zones, expansion zones, torsion zones and as articulated joints, with the connection element (2) is of a rigid, including a flexurally rigid, material. The helical recess of the flexible tubular body (2) is formed as at least one of a groove-like helical recess and as an open helical aperture of the wall (FIG 3). Two material recesses are formed on the flexible tubular body (2) as at least one of a groove-like recess and as an open aperture arranged twin-track helically inside each other (FIG 3).

The system further comprises at least one of a sleeve comprising an elastic biocompatible material made of an elastomer surrounding the tubular body and a core (4) comprising of an elastic biocompatible material, wherein at least one of the sleeve and the core (4) are held by end plates arranged on the tubular body (FIG 3). The first rigid part (5) has an external diameter (16) different from an external diameter (20) of the second rigid part (6). The internal threads (24) on the flexible tubular body (2) extend along substantially an entire length of the inner surface of the tubular body, and the helical recess extends along an entire length of the tubular body from the first end to the opposing second end (FIG 3).

However, Struder fails to disclose that the system additionally comprises a space holder for replacing a spinal disc adjacent to the connection element. Ferree discloses a spinal implant system (FIG 9A; FIG 9B) comprising a spinal stabilization device and a space holder (FIG 9A; FIG 9B) for replacing a spinal disc adjacent to the connection element. It therefore would have been obvious to one skilled in the art to modify the system taught by Struder to additionally comprise a space holder, as is taught by Ferree, because the spinal stabilization device in combination with the space holder preserves motion of the space holder while "decreasing forces across the facet joints" thereby providing a mitigating measure for pain relief after the space holder is inserted (Ferree; Paragraph [0035]).

Struder in view of Ferree fail to disclose the structure of the space holder. Gordon discloses a space holder for replacing a spinal disc having a tubular body with a flexible section having a helical recess (FIG 3). The tubular body of the space holder has a tubular wall defining a plurality of holes through the wall, wherein the helical recess of the space holder is separate from the plurality of holes (FIG 3), with the tubular body of the space holder further including a first end portion configured to engage a body part and a second end portion configured to engage an adjacent body part (FIG 2). The first end portion and the second end portion comprise projections (108) having triangular serrations. Additionally, at least one of the first end portion and the second end portion is a continuous one-piece extension of the tubular body of the space holder (FIG 3). It therefore would have been obvious to one skilled in the art to modify Struder in view of Ferree to have the space holder be that taught by Gordon because it allows for rotation,

flexure, and bending of the patient to match the characteristics of a normal vertebral disc (Gordon; Column 4).

Struder in view of Ferree and Gordon fail to disclose the specific material forming the connection element (2). It would have been obvious to one having ordinary skill in the art at the time the invention was made to have the connection element be made of titanium and alloys thereof as well as plastics, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416

Additionally, Struder in view of Ferree and Gordon fail to disclose the extent of which the tube-like body (2) is extensible or compressible. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have the tube-like body be extensible or compressible by 0.5 to 20%, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980). Furthermore, Struder in view of Ferree and Gordon fail to disclose the extent to which the tube-like body is torsionable/can pivot about the axial axis. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have the tube-like body be torsionable/can pivot about the axial axis by 0.5 to 10 degrees, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

Finally, Struder in view of Ferree and Gordon fail to disclose that the projections of the space holder are trapezoidal. It would have been an obvious matter of design

choice to one skilled in the art at the time the invention was made to construct the projections in the shape of a trapezoid, since applicant has not disclosed that such solve any stated problem or is anything more than one of numerous shapes or configurations a person ordinary skill in the art would find obvious for the purpose of providing projectins on the space holder. *In re Dailey and Eilers*, 149 USPQ 47 (1966).

Response to Arguments

7. Applicant's arguments with respect to claims 4-9, 12-18, and 23-34 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ELANA B. FISHER whose telephone number is (571)270-3643. The examiner can normally be reached on Monday through Friday from 8:30AM to 5:00PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on (571)272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Elana B Fisher/
Examiner, Art Unit 3733
/Eduardo C. Robert/
Supervisory Patent Examiner, Art Unit 3733